Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

EXPEDITED REVIEW

Research activities involving no more than minimal risk to human participants and involving only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review process (45CFR46.110 and 21CFR56.110).

EXPEDITED CATEGORIES
CATEGORY 1
Studies of drugs and medical devices only when (a) research on drugs for which an IND is not required, or (b) medical devices when (i) an IDE is not required; or (ii) the medical device is being used in accordance with its approved labeling.
CATEGORY 2
Collection of blood samples by finger/heel/ear stick or venipuncture (a) from healthy, non-pregnant adults ≥ 110 lbs, ≤550 ml in an 8 week period, not more frequently than 2 x per week; or (b) other adults and children, considering age/weight/health, collection procedure, amount of blood, frequency collected – may not exceed lesser of 50 ml or 3 ml/kg in 8 week period and not more frequently than 2 x/week.
CATEGORY 3
Prospective collection of specimens for research by non-invasive means – hair, nails, teeth, excreta/secretions, saliva, placenta, amniotic fluid, dental plaques, buccal scraping/swabs, sputum after saline mist nebulization.
CATEGORY 4
Collection of data through noninvasive procedure (no general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves. Examples: physical sensors applied to body surface with no input of significant amounts of energy, ECG, MRI, weighing or testing sensory acuity, EEG, US, blood flow.
CATEGORY 5
Research involving data/documents/records/ specimens that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
CATEGORY 6
Collection of data from voice, video, digital, or image recordings made for research purposes.
CATEGORY 7
Research on individual or group characteristics or behavior (perception, cognition, motivation, identity, language, communication, beliefs or practices, social behavior) or research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, quality assurance methodologies.
CATEGORY 8
Continuing review of research previously approved by IRB (a) where (i) it's permanently closed to enrollment (ii) subjects have completed all research related interventions (iii) is active only for long-term follow-up; or (b) where no subjects have been enrolled and no additional risks have been identified or (c) the remaining research is limited to data analysis.
CATEGORY 9
Continuing review of research not under an IND or IDE where categories 2-8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

PROCEDURES

An IRB may use the expedited review procedures to review proposals that fall within the requirements as set forth in 45CFR46.110:

- Research involving no more than minimal risk that falls into one of the above categories;
- Minor changes in previously approved research that is not expired; and,
- Major changes to previously approved research, which do not necessarily increase risk.

Expedited review will be conducted by the IRB Chair, Vice Chair, or an experienced member of the IRB designated by the Chair or Vice Chair.

The expedited review procedure cannot be used in projects where the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risk is minimal.

For minor changes in previously approved expedited research projects, amendments may be approved via expedited process if all of the following are met:

1. The proposed change does not significantly alter the risk to benefit assessment the Prisma IRB relied upon to approve the protocol;
2. The proposed change does not significantly affect the safety of the subjects;
3. The proposed change does not involve the addition of invasive procedures;
4. The proposed change does not involve the addition of procedures, interactions or interventions that add significant medical, social or psychological risks;
5. The proposed change does not involve addition of a vulnerable population in research not otherwise eligible for expedited review; and,
6. The proposed change does not significantly alter the scientific question or the scientific quality of the study.